MAY 3 0 2001

K016639 p 1/2

510 (K) Summary of Safety and Effectiveness

Company Name:	Spinal Innovations, Inc. 7850 Stage Hills Blvd. Suite 105 Bartlett, TN 38133 (901) 373-8855 (901) 373-8303 fax
510(k) Contact:	Kenneth Russell Vice President of Regulatory And Clinical Affairs (901) 373-8855
Trade Name:	Spinal Innovations Convergence™ Cervical Spinal System
Common Name:	Plate and Screw Cervical Spinal Fixation System
Classification:	888.3060 Spinal Intervertebral Body Fixation Orthosis - classII
Device Product Code:	87 KWQ
Predicate Devices:	Sofamor Danek Orion™ Anterior Cervical Plate System, Sofamor Danek Atlantis™ Anterior Cervical Plate System, Synthes Cervical Spine Locking Plate System, and DePuy Motech PEAK™ Polyaxial Anterior Cervical Plate.

Device Description

The Spinal Innovations Convergence™ Cervical Spinal System is intended for anterior intervertebral body screw fixation of the cervical spine. This system includes plates in varying designs and screws of two diameters and varying lengths. Plates have two designs: Standard Cervical Plates and Multi-Level Cervical Plates. The Cervical Screws have two diameters of 4.0 mm and 4.5 mm. The Cervical Screws are cancellous bone screws with their respective locking means to the plate assembled to the plates during the manufacturing process.

Intended Use

The Spinal Innovations Convergence™ Cervical Spinal System is intended for anterior intervertebral body screw fixation of the cervical spine. The system implants are indicated for use in the temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures or dislocation), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions.

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Testing

Biomechanical testing demonstrated that the components of the Spinal Innovations Convergence™ Cervical Spinal System exhibit equivalent mechanical performance, compared to predicate devices.

Basis for Substantial Equivalence

The Spinal Innovations Convergence™ Cervical Spinal System is substantially equivalent in material, design and function to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2001

Mr. Kenneth Russell
Vice President, Regulatory Affairs
Spinal Innovations, LLC
7850 Stage Hills Boulevard
Suite 105
Bartlett, Tennessee 38133

Re: K010639
Trade Name: Spinal Innovations Convergence™ Cervical Spinal System
Regulation Number: 21 CFR 888.3060
Regulatory Class: Class II
Product Code: KWQ
Dated: February 16, 2001
Received: March 2, 2001

Dear Mr. Russell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number K010639

Device Name: Spinal Innovations Convergence™ Cervical Spinal System.

Indications for Use:

The Spinal Innovations Convergence™ Cervical Spinal System is intended for anterior intervertebral body screw fixation of the cervical spine. The system implants are indicated for use in the temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures or dislocation), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions.

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(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010639

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(per 21 CFR 801.109)

(Optional Format 1-2-96)